DEC 17 2010

510(k) Summary of Safety and Effectiveness for the Dimension Vista® DGTX CAL

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K103360

B. Date of Preparation:

C. Proprietary and Established Names:

Dimension Vista® DGTX CAL

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Rose T. Marinelli, Regulatory Technical Specialist

Office Number: (302) 631-8805 fax Number: (302) 631-6299

E. Regulatory Information:

Drug Calibrator II:

1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Immunology

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® DGTX CAL is the Dimension® Drug Calibrator II cleared under k033809.

G. Device Description:

The DGTX CAL is a liquid bovine serum based product containing digitoxin.

H. Intended Use:

The DGTX CAL is an *in vitro* diagnostic product for the calibration of digitoxin on the Dimension Vista® System.

I. Substantial Equivalence Information:

The Dimension Vista® DGTX CAL was compared to the predicate, Dimension® Drug Calibrator II. The following table provides a comparison of the important similarities and differences:

Feature	Dimension Vista® DGTX CAL	Drug Calibrator II (DC49D) (k033809) (predicate device)
Intended Use	The DGTX CAL is an *in vitro* diagnostic product for the calibration of digitoxin on the Dimension Vista® System.	Drug Calibrator II is an *in vitro* diagnostic product intended for the calibration of the following methods packaged in Flex® reagent cartridges: • Acetaminophen (ACTM) • Carbamazepine (CRBM) • Digitoxin (DGTX) • Gentamicin (GENT) • Lidocaine (LIDO) • N-acetylprocainamide (NAPA) • Procainamide (PROC) • Tobramycin (TOBR) • Valproic Acid (VALP) • Vancomycin (VANC)
Matrix	Bovine Serum base	Bovine Serum base
Levels	5 Levels	5 Levels
Preparation	Liquid	Liquid
Storage	2 – 8 °C	2 – 8 °C

J. Conclusion:

The Dimension Vista® DGTX CAL is substantially equivalent to the current Dimension® Drug Calibrator II cleared under k033809. The Dimension Vista® DGTX CAL product is the exact same formulation as Dimension® Drug Cal II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Siemens Healthcare Diagnostics Inc.
c/o Ms. Rose Merinelli, Regulatory Technical Specialist
PO Box 6101
MS 514
Newark, DE 19714-6101

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

DEC 17 2010

Re: k103360

Trade/Device Name: Dimension Vista® Digitoxin Calibrator – DGTX CAL
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 12, 2010
Received: November 16, 2010

Dear Ms. Merinelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): 103360

Device Name: Dimension Vista® Digitoxin Calibrator, DGTX CAL (KC470)

Indications for Use: The DGTX CAL is an *in vitro* diagnostic product for the calibration of digitoxin on the Dimension Vista® System.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103360